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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,629	03/09/2004	Youngro Byun	T9983.A	4749
20450	7590	09/21/2007		
ALAN J. HOWARTH P.O. BOX 1909 SANDY, UT 84091-1909			EXAMINER SELLMAN, CACHET I	
			ART UNIT	PAPER NUMBER
			1762	
			MAIL DATE	DELIVERY MODE
			09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,629	Applicant(s) BYUN ET AL.	
	Examiner Cachet I. Sellman	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 5 recites the limitation "the first layer" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (US 2002/0091433) in view of Bernacca et al. (US 6251142).

Ding et al (US 2002/0091433) teaches a process for forming a drug release coated stent. The coating on the stent comprises a hydrophobic biostable elastomeric material and a biologically active material (abstract and 0016). The coating is applied to the stent by dipping or spraying using evaporative solvent materials [0017]. The biologically active material can be antithrombotics, anticoagulants, antiplatelet agents, thrombolytics, antiproliferatives, antiinflammatories etc. [0024]. Ding et al. teaches that various combinations of polymer materials and biologically active species can be used depending on the desired effects [0026]. The release of the active agent can be controlled by varying the thickness of the layers, the mixing method, the combination of matrix polymers, amount of bioactive material, etc [0029]. In one embodiment, a heparin system is formed by combining finely ground heparin crystals with a polysiloxane in solvent and is applied to a stent and is further cured [0058-59]. Ding et al. teaches that several applied layers of the composition makes up a tie layer and additional upper layers can be applied which are made of a different bioactive material [0080]. Ding et al. teaches that the stent coatings can be prepared using a combination of two or more drugs to control the rate of release as an example, an antiproliferation drug may be combined in the tie layer and an antiplatelet drug (i.e. heparin) in the top layer. Hydrophobic materials are preferred because the release of the active species can be more predictably controlled with those materials [0095].

Ding et al. fails to teach that the stent is washed with a washing agent prior to coating as required by **claim 1**. However, it was well known in the art at the time the invention was made to clean a stent prior to coating in order to remove contaminants and to insure that the coatings will adhere to the stent such as taught by Bernacca et al. (US 6251142) therefore one would have been motivated to wash the stent as taught by Bernacca et al. prior to coating in order to ensure sufficient adherence of the coating to the stent.

As stated above Ding et al. teaches the use of mixing more than one bioactive ingredient in the first layer as required by **claim 2**. The layers can be deposited by spraying or dipping the stent as required by **claims 3-4**.

Ding et al. teaches that the coated stents as taught above can be used to inhibit thrombosis [0024] as required by **claims 6-7**.

7. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan et al. (US 5833651) in view of Yang et al (US6258121) Bernacca et al. (US 6251142).

Donovan et al. teaches a process for forming therapeutic stents. The stents are covered with a first polymer composition comprising fibrin to provide sustained release of virus (col. 6, lines 54-57). Donovan et al. teaches that a stent can be covered with a first polymeric composition such as polylactic acid with or without heparin or another coagulation inhibitory or anti-inflammatory compound. The a second covering polymer is applied having a greater sustained release capabilities is applied over the first coating (col. 14, lines 35-55). Donovan et al. teaches that these layers can be applied by

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dipping or spraying. The stents of the invention can be used to treat various disorders as those stated in col. 12, lines 13-34).

Donovan et al. fails to teach that the stent is washed with a washing agent prior to coating as required by **claim 1**. However, it was well known in the art at the time the invention was made to clean a stent prior to coating in order to remove contaminants and to insure that the coatings will adhere to the stent such as taught by Bernacca et al. (US 6251142) therefore one would have been motivated to wash the stent as taught by Bernacca et al. prior to coating in order to ensure sufficient adherence of the coating to the stent.

Yang et al. teaches a polymeric coating for controlling the release an active agent. The stent is coated with a hydrophilic coating which has a faster rate of release and a second coating which is hydrophobic and has a slower rate of release (abstract). The active agent can an anti thrombogenic agent, anti-angiogenesis, anti-proliferative etc. such as heparin (col. 4, lines 28-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Donovan et al to include the slow release hydrophobic layer of Yang et al. One would have been motivated to do so because both are directed towards controlling the release of drugs on stents and Donovan et al. teaches using a slower release layer over the first layer while Yan get al. teaches hydrophobic layers have slower releases of active agents.

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The coating can be applied using spraying or dipping as required by **claims 3-4**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cachet I. Sellman whose telephone number is 571-272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1762

cis

/William Phillip Fletcher III/
Primary Examiner

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September 3, 2007